



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2011-0949; FRL-9361-7]

#### Alkyl Amines Polyalkoxylates; Exemption from the Requirement of a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation amends the exemption from the requirement of a tolerance for residues alkyl amines polyalkoxylates under 40 CFR 180.920 and 40 CFR 180.930 to include the additional Chemical Abstract Service Registry Number (CAS Reg. No.) 1266162-49-5. BASF Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an amendment to an existing requirement of a tolerance.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

#### SUPPLEMENTARY INFORMATION).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2011-0949 is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal

holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Fertich, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 347-8560; email address: [fertich.elizabeth@epa.gov](mailto:fertich.elizabeth@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

#### *B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at

*[http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).*

### *C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0949 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any CBI) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0949, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## II. Petition for Exemption

In the **Federal Register** of March 14, 2012 (77 FR 15012) (FRL-9335-9), EPA issued a notice pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 1E7931) by BASF Corporation, 100 Campus Drive; Florham Park, NJ 07932. The petition requested that 40 CFR 180.920 and 180.930 be amended by modifying an exemption from the requirement of a tolerance for residues of N,N-Bis- $\alpha$ -ethyl- $\omega$ -hydroxypoly(oxy-1,2-ethanediyl) C8-C18 saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl) content is 2-60 moles (CAS Reg. Nos. 10213-78-2, 25307-17-9, 26635-92-7, 26635-93-8, 288259-52-9, 58253-49-9, 61790-82-7, 61791-14-8, 61791-24-0, 61791-26-2, 61791-31-9, 61791-44-4, 68155-33-9, 68155-39-5, 68155-40-8, 70955-14-5, 73246-96-5); herein referred to as alkyl amines polyalkoxylates. Specifically, the petition requested that the exemption also include the alkyl amines polyalkoxylate described by CAS Reg. No. 1266162-49-5. That notice referenced a summary of the petition prepared by BASF Corporation, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

In this petition, BASF Corporation claims that the chemical represented by CAS Reg. No. 1266162-49-5 (poly(oxy-1,2-ethandiyl),  $\alpha,\alpha'$ -[[2-propylheptyl)imino]di-2,1-ethandiyl]bis[ $\omega$ -hydroxy-) is covered by the published tolerance exemption for alkyl amines polyalkoxylates and that no further data or review is required to amend the existing tolerance exemption to include the additional CAS Reg. No.

### **III. Inert Ingredient Definition**

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

### **IV. Aggregate Risk Assessment and Determination of Safety**

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This

includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for alkyl amine polyalkoxylates including exposure resulting from the exemption established by this

action. EPA's assessment of exposures and risks associated with alkyl amine polyalkoxylates follows.

The Agency agrees with the petitioner that CAS Reg. No. 1266162-49-5 is an alkyl amine polyalkoxylate similar to the other alkyl amine polyalkoxylates present in the exemption for N,N-Bis- $\alpha$ -ethyl- $\omega$ -hydroxypoly(oxy-1,2-ethanediyl) C8-C18 saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl) content is 2-60 moles (CAS Reg. Nos. 10213-78-2, 25307-17-9, 26635-92-7, 26635-93-8, 288259-52-9, 58253-49-9, 61790-82-7, 61791-14-8, 61791-24-0, 61791-26-2, 61791-31-9, 61791-44-4, 68155-33-9, 68155-39-5, 68155-40-8, 70955-14-5, 73246-96-5). In 2009, in establishing the exemption for the alkyl amine polyalkoxylates, EPA assessed the safety of the alkyl amine polyalkoxylates generally using worst case exposure assumptions. (74 FR 28616) (FRL-8418-6). EPA concluded that that assessment showed that exempting the alkyl amine polyalkoxylates from the requirement from a tolerance would be safe. Inclusion of chemical described by the CAS Reg. No. 1266162-49-5 in the risk assessment for the alkyl amine polyalkoxylates would in no way alter that prior risk assessment given the generic findings on toxicity and the worst case exposure assumptions used in that risk assessment. Accordingly, based on the findings in that earlier rule, EPA has determined that there is a reasonable certainty that no harm to any population subgroup, including infants and children, will result from aggregate exposure to alkyl amine polyalkoxylates, including the chemical described by the CAS Reg. No. 1266162-49-5, under reasonably foreseeable circumstances. Therefore, the amendment of an exemption from tolerance under 40 CFR 180.920 and 180.930 for residues of alkyl amine polyalkoxylates to

include the chemical described by the CAS Reg. No. 1266162-49-5 is safe under FFDCA section 408.

## **V. Other Considerations**

### *A. Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for alkyl amine polyalkoxylates.

## **VI. Conclusions**

Therefore, the exemption from the requirement of a tolerance under 40 CFR 180.920 and 180.930 for alkyl amine polyalkoxylates is amended to include CAS Reg. No. 1266162-49-5.

## **VII. Statutory and Executive Order Reviews**

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the

relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

#### **VIII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 28, 2012.

Lois Rossi,  
*Director, Registration Division, Office of Pesticide Programs*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In §180.920, the table is amended by revising the following inert ingredient to read as follows:

**§180.920 Inert ingredients use pre-harvest; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

Inert ingredients	Limits	Uses
<p>* * * * *</p> <p>N,N-Bis-<math>\alpha</math>-ethyl-<math>\omega</math>-hydroxypoly(oxy-1,2-ethanediyl) C8-C18 saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl) content is 2-60 moles (CAS Reg. Nos. 10213-78-2, 25307-17-9, 26635-92-7, 26635-93-8, 288259-52-9, 58253-49-9, 61790-82-7, 61791-14-8, 61791-24-0, 61791-26-2, 61791-31-9, 61791-44-4, 68155-33-9, 68155-39-5, 68155-40-8, 70955-14-5, 73246-96-5, 1266162-49-5)</p> <p>* * * * *</p>	<p>Not to exceed 25% in herbicide formulations and 10% in insecticide and fungicide formulations</p>	<p>Surfactants, related adjuvants of surfactants</p>

3. In §180.930, the table is amended by revising the following inert ingredient to read as follows:

**§180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

Inert ingredients	Limits	Uses
<p>* * * * *</p> <p>N,N-Bis-<math>\alpha</math>-ethyl-<math>\omega</math>-hydroxypoly(oxy-1,2-ethanediyl) C8-C18 saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl) content is 2-60 moles (CAS Reg. Nos. 10213-78-2, 25307-17-9, 26635-92-7, 26635-93-8, 288259-52-9, 58253-49-9, 61790-82-7, 61791-14-8, 61791-24-0, 61791-26-2, 61791-31-9, 61791-44-4, 68155-33-9, 68155-39-5, 68155-40-8, 70955-14-5, 73246-96-5, 1266162-49-5)</p> <p>* * * * *</p>	<p>Not to exceed 25% in herbicide formulations and 10% in insecticide and fungicide formulations</p>	<p>Surfactants, related adjuvants of surfactants</p>